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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of: Pettis *et al.*

Confirmation No.: 4733

RECEIVED

Serial No. 09/893,746

Art Unit: 3763

AUG 25 2003

Filed: June 29, 2001

Examiner: Mendez, Manuel A.

For: METHODS FOR ALTERING DRUG
PHARMACOKINETICS BASED ON
MEDICAL DELIVERY PLATFORM

Attorney Docket: P4901-P1
(11219-0021-999)

SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT

UNDER 37 C.F.R. §1.56 and §1.97

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Sir:

In accordance with the duty of disclosure imposed by 37 C.F.R. § 1.56 and § 1.97 to inform the Patent and Trademark Office of all references coming to the attention of each individual associated with the filing or prosecution of the subject application, which are or may be material to the patentability of any claim of the application, Attorneys for Applicants hereby direct the Examiner's attention to the references BR-CL listed on the attached revised form PTO 1449. A copy of each references BR-CL is provided herewith.

Identification of the listed reference is not to be construed an admission of Applicants or Attorneys for Applicants that such reference is available as "prior art" against the subject application. Consequently, Applicants respectfully decline to use form PTO-1449, since this form identifies all of the references cited therein as "Prior Art". As an alternative, Applicants submit herewith a "revised form PTO 1449" entitled "List of References Cited" instead of "List of Prior Art Cited".

Applicants respectfully request that the Examiner review the foregoing references and that the references be made of record in the file history of the application.

Please charge the required fee to Pennie & Edmonds LLP Deposit Account No.
16-1150. A duplicate copy of this sheet is enclosed for accounting purposes.

Respectfully submitted,

by *Jacqueline Penn*
Reg No. 43,492

Date: August 21, 2003

Laura A. Coruzzi 30,742
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Enclosures

LIST OF REFERENCES CITED BY APPLICANT
(Use several sheets if necessary)

ATTY DOCKET NO.

11219-021-999 (P4901-P1)

APPLICATION NO

09/893,746

APPLICANT

Pettis *et al.*

FILING DATE

June 29, 2001

GROUP

3763

U.S. PATENT DOCUMENTS

| *EXAMINER INITIAL | | DOCUMENT NUMBER | DATE | NAME | CLASS | SUBCLASS | FILING DATE IF APPROPRIATE |
|----------------------|----|-----------------|----------|--------------|-------|----------|-------------------------------|
| | BR | 6,319,224 | 11/20/01 | Stout et al. | | | |
| | BS | US 2003/0073609 | 4/17/03 | Pinkerton | | | |

FOREIGN PATENT DOCUMENTS

| | | DOCUMENT NUMBER | DATE | COUNTRY | CLASS | SUBCLASS | TRANSLATION |
|--|--|-----------------|------|---------|-------|----------|-------------|
| | | | | | | | YES NO |

OTHER REFERENCES (Including Author, Title, Date, Pertinent Pages, Etc.)

| | | |
|--|----|--|
| | BT | Bader M. Influenza vaccine experience in Seattle. Am. J. Public Health. 1980 May;70(5):545 |
| | BU | Brooks et al. Intradermal administration of bivalent and monovalent influenza vaccines. Ann. Allergy. 1977 Aug; 39(2):110-2 |
| | BV | Brown et al. The immunizing effect of influenza A/New Jersey/76 (Hsw1N1) virus vaccine administered intradermally and intramuscularly to adults. J. Infect. Dis. 1977 Dec;136 Suppl:S466-71 |
| | BW | Crowe Experimental comparison of intradermal and subcutaneous vaccination with influenza vaccine. Am. J. Med. Technol. 1965 Nov-Dec;31(6):387-96 |
| | BX | Foy et al. Efficacy of intradermally administered A2 Hong Kong vaccine. JAMA. 1970 Jul 6;213(1):130 |
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| | BZ | Gramzinski et al. Immune response to a hepatitis B DNA vaccine in Aotus monkeys: a comparison of vaccine formulation, route, and method of administration. Mol. Med. 1998 Feb;4(2):109-18 |
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| | CC | McElroy et al. Response to intradermal vaccination with A2, Hong Kong variant, influenza vaccine. N. Engl. J. Med. 1969 Nov 6;281(19):1076 |
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| | CI | Merriam-Webster's Collegiate Dictionary, 10 th Edition, 1998, Merriam-Webster, Inc., Springfield, MA, p. 306 |
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| | CL | Marian et al. 2001, Acta Biologica Hungarica, 52(1): 35-45 |

EXAMINER

DATE CONSIDERED

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.